

REMARKS

This is in response to the Office Action dated July 17, 2008. In view of the foregoing amendments and following representations, reconsideration is respectfully requested.

By the above amendments, claims 46, 47, 48, 50, 51, 52, 53, 55, 59, 60, 61 and 62 are amended; and claims 49, 54, 57, 58 and 63 are cancelled. Thus, upon entry of the above amendments, claims 46-48, 50-53, 55 and 59-62 will be pending in the present application.

On pages 2-3 of the Office Action, the specification is objected to due to inconsistencies in the permeability units. Accordingly, page 5 has been amended to provide the correct unit, i.e., “ml/cm² 24 hr atm.” Also, page 18 has been amended to provide antecedent basis for the claim terminology, i.e., “discharge part” and “closing member”.

Next, on page 3 of the Office Action, claims 47, 53, 56 and 62 are objected to because of the permeability unit. Accordingly, as per the Examiner’s suggestion, these claims have been amended to recite the permeability as “ml/cm² 24 hr atm.”

Further, claims 50-52 have been amended to clarify the location of the permeability region. For example, claim 50 now clearly indicates that the gas permeable region of the main body is provided at a plurality of separate locations in the main body and each portion extends in a direction of an axis of the vessel.

Next, on pages 3-10 of the Office Action, claims 46-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickhard (U.S. Patent No. 5,147,311) in view of the Dow Corning article and Codner (U.S. 5,686,304) in view of Baidwan et al. (U.S. 4,299,238), Karakashian (U.S.

3,937,219) and Polak (U.S. Patent No. 5,114,421). It is submitted that the present invention, as embodied by the amended claims, now clearly distinguishes over the applied references for the following reasons.

Independent claim 47 has been amended to require, *inter alia*, that the main body includes a gas permeable region comprising a porous film made of one or more of the group consisting of polytetrafluoroethylene, tetrafluoroethylene-hexafluoropropylene copolymer, polyethylene terephthalate, polypropylene, polyethylene, and hydrophobic polyvinylidene fluoride.

Similarly, independent claim 55 has been amended to require, *inter alia*, that the main body includes a gas permeable region comprising a porous film made of one or more of the group consisting of polytetrafluoroethylene, tetrafluoroethylene-hexafluoropropylene copolymer, polyethylene terephthalate, polypropylene, polyethylene, and hydrophobic polyvinylidene fluoride.

The amendments to claims 46 and 55 set forth the specific materials forming the film that comprises the gas permeable region in the main body. As will be discussed below, one of ordinary skill in the art would recognize the vast differences in the gas permeability of the materials recited in claims 46 and 55 and the gas permeability of the pharmaceutical rubber or silicone employed in the Pickhard reference.

Pickhard discloses an injection device including a housing 2, a holder 3, and an ampoule 4 (with tubular member 13 and bellows section 14) that is screwed into the holder. A combination seal and holder 15 is attached to the main section of the ampoule via weld 16. The seal and holder includes parts 17 and 18 that form a rupturable barrier formed of pharmaceutical rubber or a similar material. Further, as described in col. 8, lines 12-28, the bellows member of ampoule 4 is formed of

a deformable plastic-pharmaceutical rubber, silicone, or a similar material. Part 17 is made of a resiliently deformable plastic, silicone and the like, while part 18 is made from a more stable and rigid plastic PVC or similar material. Thus, it is clear that the Pickhard ampoule/injection device is not suitable for holding a fluid handling medium that contains cells. As will be explained below, the materials forming the components of the Pickhard injection device are vastly different in permeability than the materials used to form the gas permeable regions recited in claims 46 and 55. Furthermore, Pickhard lacks a plunger having a gas permeable region for passing a quantity of gas necessary for survival of the cells, and a main body that includes a gas permeable region comprising a porous film made of one or more of the group consisting of polytetrafluoroethylene, tetrafluoroethylene-hexafluoropropylene copolymer, polyethylene terephthalate, polypropylene, polyethylene, and hydrophobic polyvinylidene fluoride.

In general, the gas permeability level of a silicone resin can be measured using a gas chromatography apparatus. However, each of the materials recited in the independent claims, i.e. each resin of polytetrafluoroethylene, tetrafluoroethylene -hexafluoropropylene copolymer, polyethylene terephthalate, polypropylene, polyethylene, and hydrophobic polyvinylidene fluoride (hereinafter, referred to as "gas permeable resin of the present application") has gas permeability that is so high that it cannot be measured by a gas chromatography apparatus. The difference between these two permeability levels is so large that, for example, the permeability of the gas permeable resins of the present application can be measured just by applying a slight wind pressure.

Thus, it is submitted that one of ordinary skill in the art would recognize the enormous

difference between the respective permeability levels. Note that the difference between the respective permeability levels is so significant that data, which would allow a comparison using the same index, is not available.

Further, by using the gas permeable resins of the present application, "contamination of the cell suspension 100 due to the intrusion of bacteria can be prevented", and in addition, "the gas permeable film can be made to be both gas permeable and cell non-adhesive" (see page 22, line 23 to page 23, line 12 of the present specification). Furthermore, when a porous film is used in the gas permeable areas, cells can be stored safely rather than being destroyed, because the gas permeable region 21 enables the bubbles to be exhausted to the exterior and disposed of while preventing contamination" (see page 24, line 23 to page 25, line 2 of the present specification).

Also, as described in the specification, the "gas permeable film 20 need not be cylindrical, but can also be provided by combining strips of film and the exterior side of the cylindrical body 3 so as to cover each of the slits 31, making them liquid-tight". When the gas permeable region is provided as a partial component with respect to the cylindrical body 3, it is a common knowledge in the art that a cylindrical body made of polypropylene or the like and the gas permeable resin of the present application need to be integrated. Specifically, methods such as thermal adhesion, fusion and the like are available. However, such integration cannot be achieved when using a silicone resin. Thus, the gas permeable resin of the present application has a considerable advantage over the silicone resin used in the Pickard device.

These advantageous and unique effects of the present invention are obtained as a result of using the gas permeable resins of the present application which have extremely high gas

permeability. One of ordinary skill in the art would understand that these effects cannot be obtained merely by using silicone resin as the material for a cell handling device. Clearly, the gas permeable resin of the present invention provides "a critical characteristic that is possessed by the claimed gas permeable resin" and not by the materials employed in the applied prior art devices.

Thus, even if a person of ordinary skill in the art were to have combined the applied prior art references, i.e., Pickhard, Dow Corning, Codner, Baldwin, Karakashian, and Polak, based on the common knowledge in the art at the time of the invention, it would have led to a cell-handling apparatus having gas permeability that could only be measured by a gas chromatography apparatus. Thus, the applied references would not have resulted in the present invention, as defined in amended claims 46 and 55, which achieves a high degree of safety and superior cell storage performance. Note that the Dow Corning, Codner, Baldwin, Karakashian and Polak references are described in detail in the previous response.

Based on the above it is submitted that independent claims 46 and 55 of the present application are now clearly allowable over the prior art of record. Further, the remaining claims, depend, directly or indirectly, from one of claims 46 and 55, and are therefore allowable at least by virtue of their dependencies.

In view of the above, it is submitted that the present application is now clearly in condition for allowance. The Examiner therefore is requested to pass this case to issue.

In the event that the Examiner has any comments or suggestions of a nature necessary to place this case in condition for allowance, then the Examiner is requested to contact Applicant's undersigned attorney by telephone to promptly resolve any remaining matters.

Respectfully submitted,

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